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FEB 16 2012

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

As required by section 807.92(c)

1. SUBMITTER'S INFORMATION

Company Name and Address

Dental Photonics, Inc.

1600 Boston-Providence Hwy

Walpole, MA 02081

Phone: 781-754-7900

Official Contact

Marcy Moore

MMP Medical Associates, LLC

16 Appleton St.

Waltham, MA 02453

Phone: 919-363-2432

Date Prepared

January 24, 2012

2. DEVICE INFORMATION

Trade/Proprietary Name	*stLase*
Common/Usual Name	Dental Laser
Classification Name	LASER INSTRUMENT, SURGICAL, POWERED (21 CFR 878.4810) Class II
Product Code	GEX

3. PREDICATE DEVICE

Dental Photonics, Inc.
K094049 – stLase

4. INTENDED USE

The stLase with surgical laser operation (Automatic Power Control) that can be used in contact or non-contact technique, is indicated for dental soft tissue indications including: incision, excision, vaporization, ablation, hemostasis, or coagulation of intraoral and extraoral soft tissue (including marginal and interdental gingiva and epithelial lining of free gingiva). Examples include: frenectomy, frenotomy, biopsy, operculectomy, implant recovery/uncovery, gingivectomy, gingivoplasty, gingival troughing, crown lengthening, removal of granulation tissue, laser assisted flap surgery, debridement of diseased epithelial lining, incisions and draining of abscesses, tissue retraction for impressions, papillectomy, vestibuloplasy, excision of lesions, exposure of unerupted/partially erupted teeth, leukoplakia, removal of hyperplastic tissues, and sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket).

The *stLase with* surgical laser operation that can be used in contact or non-contact technique is intended for use in general surgery for incision/excision, vaporization, ablation and coagulation of soft tissue, and

The *stLase with* dental laser operation is intended to be used in contact or non-contact technique for incision, excision, vaporization, ablation, hemostasis, or coagulation of intraoral and extraoral soft tissue (including marginal and interdental gingiva and epithelial lining of free gingiva). Examples include: frenectomy, frenotomy, biopsy, operculectomy, implant recovery/uncovery, gingivectomy, gingivoplasty, gingival troughing, crown lengthening, hemostasis of donor site, removal of granulation tissue, laser assisted flap surgery, debridement of diseased epithelial lining, incisions and draining of abscesses, tissue retraction for impressions, papillectomy, vestibuloplasty, excision of lesions, exposure of unerupted/partially erupted teeth, leukoplakia, removal of hyperplastic tissues, treatment of aphthous ulcers, sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket), pulpotomy, pulpotomy as an adjunct to root canal therapy, and light activation of bleaching materials for teeth whitening.

5. DEVICE DESCRIPTION

The Dental Photonics *stLase* is a soft tissue surgical laser system indicated for use in dental applications. It can generate up to 25 W at 980 nm wavelength in fiberoptic output used for a variety of dental and oral surgical applications, including cutting and coagulation of intraoral and extraoral soft tissues.

6. SUBSTANTIAL EQUIVALENCE

Substantial equivalence of the *stLase* is demonstrated by similarity in technical specifications to the predicate device. The *stLase* has the same material design, mechanism of action, technical specifications and function as the predicate device: stLase Laser K094049. Bench testing and conformity to applicable standards has also been demonstrated.

Both devices are available in continuous wave or pulsed mode and may be used in contact or non-contact mode. Both devices employ a fiber delivery system consisting of a fiber optic connector, cable, handpiece and disposable adapters to hold fiber in the distal part. As can be seen in the comparison table below, there are no technical differences between the current stLase submission and the predicate stLase device.

Specification	Dental Photonics, Inc. *stLase*	Dental Photonics, Inc. *stLase*
K Number	K111689	K094049
Wavelength	980 nm	980 nm
Output power	25 W	25 W
Power range	0.5-25 W	0.5-25 W
Increments	0.1-0.5 W	0.1-0.5 W
Operating modes	Pulsed or CW	Pulsed or CW
Pulse duration	0.025 ms to 3 ms	0.025 ms to 3 ms
Timer duration	50 ms to 99.9 s	50 ms to 99.9 s
Frequency	20, 000 Hz	20,000 Hz
Aiming beam	650 nm, 5mW	650 nm, 5mW
Cooling	Air cooled, closed control water circuit	Air cooled, closed control water circuit
Weight	~ 1.8 kg (4 lbs)	~ 1.8 kg (4 lbs)
Dimensions	14"x14.2"x11"	14"x14.2"x11"
Power requirements	120V/60Hz or 240V/50Hz	120V/60Hz or 240V/50Hz
Sterilization method	Steam autoclave	Steam autoclave

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FEB 16 2012

Dental Photonics, Inc.
% MMP Medical Associates, LLC
Ms. Marcy Moore
16 Appleton Street
Waltham, Massachusetts 02453

Re: K111689
Trade/Device Name: stLase
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: February 08, 2012
Received: February 09, 2012

Dear Ms. Moore:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

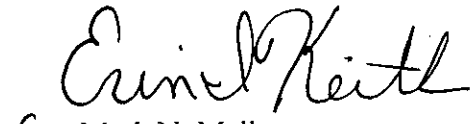
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K111689

Device Name: *stLase*

Indications for Use:

The stLase with surgical laser operation (Automatic Power Control) *that can be used in contact or non-contact technique, is indicated for dental soft tissue indications including: incision, excision, vaporization, ablation, hemostasis, or coagulation of intraoral and extraoral soft tissue (including marginal and interdental gingiva and epithelial lining of free gingiva). Examples include: frenectomy, frenotomy, biopsy, operculectomy, implant recovery/uncovery, gingivectomy, gingivoplasty, gingival troughing, crown lengthening, removal of granulation tissue, laser assisted flap surgery, debridement of diseased epithelial lining, incisions and draining of abscesses, tissue retraction for impressions, papillectomy, vestibuloplasy, excision of lesions, exposure of unerupted/partially erupted teeth, leukoplakia, removal of hyperplastic tissues, and sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket).*

The stLase with surgical laser operation that can be used in contact or non-contact technique is *intended for use in general surgery for incision/excision, vaporization, ablation and coagulation of soft tissue, and*

The stLase with dental laser operation is intended to be used in contact or non-contact technique for incision, excision, vaporization, ablation, hemostasis, or coagulation of intraoral and extraoral soft tissue (including marginal and interdental gingiva and epithelial lining of free gingiva). Examples include: *frenectomy, frenotomy, biopsy, operculectomy, implant recovery/uncovery, gingivectomy, gingivoplasty, gingival troughing, crown lengthening, hemostasis of donor site, removal of granulation tissue, laser assisted flap surgery, debridement of diseased epithelial lining, incisions and draining of abscesses, tissue retraction for impressions, papillectomy, vestibuloplasty, excision of lesions, exposure of unerupted/partially erupted teeth, leukoplakia, removal of hyperplastic tissues, treatment of aphthous ulcers, sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket), pulpotomy, pulpotomy as an adjunct to root canal therapy, and light activation of bleaching materials for teeth whitening.*

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K111689